

DTI [redacted] PCT/PTO JUN 11 2002

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: [redacted], Paul L. et al.

#3

Serial No. 10/070,220

Filed: February 27, 2002

For: HEPATITIS C VIRUS REPLICATION
INHIBITORS

Art Unit: _____

Examiner: _____

Assistant Commissioner for Patents
Washington, D.C. 20231INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR 1.97

Sir:

1. In compliance with 37 C.F.R. 1.97, submitted on the attached form herewith is a list of patents, publications or other information which are requested to be made of record in this application.

This Information Disclosure Statement is not an admission that any patent, publication or other information referred to herein is "prior art" for this invention unless specifically designated as such.

In accordance with 37 C.F.R. 1.97(h), the filing of this Information Disclosure Statement shall not be construed to be an admission that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. 1.56(b).

2. In accordance with 37 C.F.R. 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made.

3. Applicants respectfully request that the Examiner initial the attached form after reviewing the pertinence of each reference.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231, on the date appearing below.

MERCK & CO., INC.

By [Signature] Date 6/6/02



INFORMATION DISCLOSURE STATEMENT

4. The references listed on the attached form are not enclosed because they have been submitted to or cited by the Office in a related application as follows:

RELATED APPLICATION		
U. S. SERIAL NUMBER	FILING DATE	MERCK CASE

upon which the instant application relies for an earlier filing date under 35 U.S.C. 120. Therefore, pursuant to 37 C.F.R. 1.98(d), copies of these references are not enclosed herewith. If this is inconvenient, additional copies will be submitted upon request.

5. In accordance with 37 C.F.R. 1.97, (check one)

- ☐ the attached information is filed within three months of the filing date of the captioned case.
- ☒ the attached information is filed more than three months after the filing date but prior to a first Official Action on the merits.
- ☐ the attached information is being filed more than three months after the filing date and after receipt of the first Office Action on the merits, but before Final Action or Notice of Allowance. The enclosed authorization is therefore given to charge Deposit Account No. 13-2755 for the fee required under 37 C.F.R. 1.17(p).
- ☐ the undersigned certifies that each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Statement.
- ☐ the undersigned certifies that no item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to the knowledge of the person signing the certification after making reasonable inquiry, was known to any individual designated under 37 C.F.R. 1.56(c) more than three months prior to the filing of the statement.

Respectfully submitted,

Sheldon O. Heber

By: Sheldon O. Heber

Attorney _____ For Applicant(s)

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Date: June 6, 2002

INFORMATION DISCLOSURE

STATEMENT BY APPLICANT

JUN 11 2002

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Sheet

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of

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Application Number	10/000000
Filing Date	February 27, 2002
First Named Inventor	Darke, Paul L.
Group Art Unit	
Examiner Name	
Attorney Docket Number	20511P

[illegible][illegible]Date
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INFORMATION DISCLOSURE**STATEMENT BY APPLICANT**

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Attorney Docket Number

20511P

COMPLETE IF KNOWN

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Examiner Name	
Attorney Docket Number	20511P

OTHER NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.	Include name of the author, title, date, page(s), volume-issue number(s) and place of publication.
		Bartenschlager, R. et al., Complex formation between the NS3 serine-type proteinase of the hepatitis C virus and NS4A and its importance for polyprotein maturation, J. of Virology, Vol. 69, No. 12, pps 7519-7528, 1995.
		Bartenschlager, R. et al., Nonstructural protein 3 of the hepatitis C virus encodes a serine-type proteinase required for cleavage at the NS3/4 and NS4/5 junctions, J. of Virology, Vol. 67, No. 7, pps 3835-3844, 1993.
		Butkiewicz, N.J. et al., Enhancement of hepatitis c virus NS3 proteinase activity by association with NS4A-specific synthetic peptides: identification of sequence and critical residues of NS4A for the cofactor activity, Virology, Vol. 225, pps 328-338, 1996.
		Choo, Q-L. et al., Isolation of a cDNA clone derived from a blood-borne non-A, non-B viral hepatitis genome, Science, Vol. 244, pps 359-362, 1989.
		Choo, Q-L. et al., Genetic organization and diversity of the hepatitis C virus, Proc. Natl. Acad. Sci. USA, Vol. 88, pps 2451-2455, 1991.
		Darke, P.L. et al., Inhibition of hepatitis C virus NS2/3 processing by NS4A peptides, J. of Biological Chemistry, Vol. 274, No. 49, pps 34511-34514, 1999.
		D'Souza, E.D.A. et al., Analysis of NS3-mediated processing of the hepatitis c virus non-structural region in vitro, J. of General Virology, Vol. 75, pps 3469-3476, 1994.
		Gante, J., Peptidomimetics-tailored enzyme inhibitors, Angew. Chem. Int. Ed. Engl., Vol. 33, pps 1699-1720, 1994.
		Gorbalenya, A.E. et al., Viral cysteine proteinases, Perspectives in Drug Discovery and Design, Vol. 6, pps 64-86, 1996.
		Grakoui, A. et al., A second hepatitis C virus-encoded proteinase, Proc. Natl. Acad. Sci. USA, Vol. 90, pps 10583-10587, 1993.
		Hijikata, M. et al., Two distinct proteinase activities required for the processing of a putative nonstructural precursor protein of hepatitis C virus, J. of Virology, Vol. 67, No. 8, pps 4665-4675, 1993.
		Hijikata, M. et al., Proteolytic processing and membrane association of putative nonstructural proteins of hepatitis C virus, Proc. Natl. Acad. Sci. USA, Vol. 90, pps 10773-10777, 1993.
		Houghton, M. et al., Molecular biology of the hepatitis C viruses: implications for diagnosis, development and control of viral disease, Hepatology, Vol. 14, No. 2, pps 381-388, 1991.
		Ingallinella, P. et al., Potent peptide inhibitors of human hepatitis C virus NS3 protease are obtained by optimizing the cleavage products, Biochemistry, Vol. 37, pps 8906-8914, 1998.
		Kakiuchi, N. et al., Cleavage activity of hepatitis C virus serine proteinase, J. Biochem., Vol. 122, No. 4, pps 749-755, 1997.

Examiner
SignatureDate
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*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609.

Draw line through citation if not in conformance and not considered.

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Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <div style="border: 1px solid black; border-radius: 50%; padding: 5px; display: inline-block;"> JUN 11 2002 (use as many sheets as necessary) </div>		COMPLETE IF KNOWN		
		Application Number	10/000000	
		Filing Date	February 27, 2002	
		First Named Inventor	Darke, Paul L.	
		Group Art Unit		
		Examiner Name		
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OTHER NON PATENT LITERATURE DOCUMENTS		
Examiner Initials*	Cite No.	Include name of the author, title, date, page(s), volume-issue number(s) and place of publication.
		Kim, J.L. et al., Crystal structure of the hepatitis c virus NS3 protease domain complexed with a synthetic NS4A cofactor peptide, Cell, Vol. 87, pps 343-355, 1996.
		Komoda, Y. et al., Processing of hepatitis C viral polyprotein in escherichia coli, Gene, Vol. 145, pps 221-226, 1994.
		Kuo, G. et al., An assay for circulating antibodies to a major etiologic virus of human non-A, non-B hepatitis, Science, Vol. 244, pps 362-364, 1989.
		Landro, J.A. et al., Mechanistic role of an NS4A peptide cofactor with the truncated NS3 protease of hepatitis C virus: elucidation of the NS4A stimulatory effect via kinetic analysis and inhibitor mapping, Biochemistry, Vol. 36, No. 31, pps 9340-9348, 1997.
		Lin, C. et al., A central region in the hepatitis C virus NS4A protein allows formation of an active NS3-NS4A serine proteinase complex in vivo and in vitro, J. of Virology, Vol. 69, No. 7, pps 4373-4380, 1995.
		Lohmann, V. et al., Processing pathways of the hepatitis C virus proteins, J. of Hepatology, Vol. 24 (Suppl. 2), pps 11-19, 1996.
		Love, R. A. et al., The crystal structure of hepatitis C virus NS3 proteinase reveals a trypsin-like fold and a structural zinc binding site, Cell, Vol. 87, pps 331-342, 1996.
		Mizushima, H. et al., Analysis of N-terminal processing of hepatitis C virus nonstructural protein 2, J. of Virology, Vol. 68, No. 4, pps 2731-2734, 1994.
		Neddermann, P. et al., The nonstructural proteins of the hepatitis C virus: structure and functions, Biol. Chem., Vol. 378, pps 469-476, 1997.
		Pieroni, L. et al., In vitro study of the NS2-3 protease of hepatitis C virus, J. of Virology, Vol. 71, No. 9, pps 6373-6380, 1997.
		Pryor, K.D. et al., High-level expression of soluble protein in escherichia coli using a His6-tag and maltose-binding-protein double-affinity fusion system, Protein Expression and Purification, Vol. 10, pps 309-319, 1997.
		Santolini, E. et al., The NS2 protein of hepatitis C virus is a transmembrane polypeptide, J. of Virology, Vol. 69, No. 12, pps 7461-7471, 1995.
		Satoh, S. et al., The N-terminal region of hepatitis C virus nonstructural protein 3 (NS3) is essential for stable complex formation with NS4A, J. of Virology, Vol. 69, No. 7, pps 4255-4260, 1995.
		Selby, M.J. et al., Expression, identification and subcellular localization of the proteins encoded by the hepatitis C viral genome, J. of General Virology, Vol. 74, pps 1103-1113, 1993.
		Shimizu, Y. et al., Identification of the sequence on NS4A required for enhanced cleavage of the NS5A/5B site by hepatitis C virus NS3 protease, J. of Virology, Vol. 70, No. 1, pps 127-132, 1996.

Examiner Signature	Date Considered
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